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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 09/870,483 | 06/01/2001 | Norimasa Okuda | 04853.0072 | 1041 |
| 22852 | 7590 | 03/29/2004 | EXAMINER | |
| FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER LLP 1300 I STREET, NW WASHINGTON, DC 20005 | | | OH, TAYLOR V | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1625 | |

DATE MAILED: 03/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|--------------------------------------|-------------------------------------|--|
| Office Action Summary | Application No. 09/870,483 | Applicant(s) OKUDA ET AL. | |
| | Examiner Taylor Victor Oh | Art Unit 1625 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 February 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 20-42 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 20-42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2/17/2004 has been entered.

The Status of Claims

Claims 20-42 are pending.

Claims 20-42 have been rejected.

Claims 1-19 have been canceled.

Claim Objections

Claim 26 is objected to because of the following informalities: the chemical term "boracic acid" is recited. Appropriate spelling correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 27 ,28 , and 36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 27, "a saturated or unsaturated linear or branched chain hydrocarbon comprising" is recited. The expression of " comprising" is vague and indefinite. The meaning of the " comprising" would mean many additional components besides the " saturated or unsaturated linear or branched chain hydrocarbon". This is improper. An appropriate correction is required.

In claim 28, "an aromatic hydrocarbon comprising" is recited. The expression of " comprising" is vague and indefinite. The meaning of the " comprising" would mean many additional components besides the " aromatic hydrocarbon". This is improper. An appropriate correction is required.

In claim 36, " one non-miscible organic solvent comprises" is recited. The expression of " comprises" is vague and indefinite. The meaning of the " comprising" would mean many additional components besides the " one non-miscible organic solvent". This is improper. An appropriate correction is required.

Claim Rejections - 35 USC § 103

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of

the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 20-33 and 41-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kawabe et al (US 5,763,652) in view of Susumu et al ((JP10059895: translated version).

Kawa et al teaches a process for producing an alpha-hydroxycarboxylic acid by hydrolyzing an alpha nitrile compound (see col. 6 ,lines 33-40) in the presence of an acidic acid, (see col. 7 ,lines 12-14), such as hydrochloric acid, sulfuric acid, phosphoric

acid (see col. 7 ,lines 29-31). The amount of the acidic catalyst is selected from a range of 0.75 to 10 moles per mole of the nitrile compound (see col. 7 ,lines 46-50) and the amount of water relative to 1 mole of the nitrile compound is 1.5 to 50 moles (see col. 7 ,lines 52-57). The hydrolysis reaction can be carried out at a temperature of 50 to 150⁰ C(see col. 8 ,lines 13-14) in an inert solvent , such as hexane, benzene, xylene, toluene and other aromatic hydrocarbons, and etc.; these solvents may employed singly or in combination (see col. 8, lines 1-11).

However, the instant invention differs from the prior art in that the reaction mixture contains less than 10 % by weight of an organic solvent;

Susumu et al teaches a process of producing an optically active 4-phenyl mandelic acid by reacting 10 g (55 millimol) of 4-phenyl benzaldehyde, 10 ml (8.7 g) of toluene, 11.4 ml (0.13 mols) of concentrated hydrochloric acid, and 5.4 g (83 millimol) of potassium cyanides in 10 ml of water at 15 to 20⁰ C; after 90 mins, 60 ml (0.69 mols) of concentrated hydrochloric acid has been introduced in the reaction mixture and heated at 75-80⁰ C (see page 3 , paragraph 30). Furthermore, during the process, a nitrile compound is formed (see page 2 , formula 5). As a solvent system, ethyl acetate, toluene, an acetic acid, methanol, ethanol, and water or those mixed solvents can be used 0.5 to 5 weight % to the aldehyde derivative (see page 3 ,paragraph 16).

Kawa et al expressly teaches the process for producing the alpha-hydroxycarboxylic acid by hydrolyzing the alpha-nitrile compound (see col. 6 ,lines 33-40) in the presence of the acidic acid and the mixed organic solvents. Also, Susumu et al does disclose the process of producing the 4-phenyl mandelic acid by hydrolyzing the intermediate cyanohydrin compound in the presence of the acidic catalyst and the mixed solvents in the amount of 0.5 to 5 weight % to the aldehyde derivative. Both prior art have shared the common process of producing the alpha-hydroxycarboxylic acid with similar reaction conditions : the acidic catalyst, the hydrocarbon solvent system, and the overlapped reaction temperature.

Therefore, in order to optimize the organic solvent system by a routine experimentation, it would have been obvious to the skilled artisan in the art to have motivated to incorporate the organic solvent weight % of Susumu et al into the Kawa et al process , thereby producing the desired optically active alpha-hydroxycarboxylic acid from the alpha-nitrile compound. This is because the skilled artisan in the art would expect a similar success as shown in the case of the Susumu et al process.

Claims 34-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Susumu et al ((JP10059895: translated version).

Susumu et al teaches a process of producing an optically active 4-phenyl mandelic acid by reacting 100 g (0.549 mol) of 4-phenyl benzaldehyde, 200 ml (8.7 g) of ethyl acetate, 43 g (0.66 mol) of potassium cyanides in 120 ml of water at 15 to 20 ° C; subsequently, 360 g (3.5 mols) of concentrated hydrochloric acid and 215 g of acetic acids have been introduced in the reaction mixture and heated at 80-85° C to form the

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desired product(see page 3 , paragraph 30). The resultant mixture has been cooled at 25° C and 4-phenyl mandelic acid crystals have been recovered by crystallization , filtration, back washing by water and by drying (see page 5 , paragraph 35). As a solvent system for the process, ethyl acetate, toluene, an acetic acid, methanol, ethanol, and water or those mixed solvents can be used 0.5 to 5 weight % to the aldehyde derivative (see page 3 ,paragraph 16).

However, the instant invention differs from the prior art in that the ratio of the volume of the aqueous solution to that of the non-miscible organic solvent ranges from 1: 0.05 to 1:1, the crystallization takes place at a rate of 0.5° C/min and the crystalline optically active alpha-hydroxycarboxylic acid exhibits a packing density of 0.5 g/cm³.

With respect to the claimed ratio of the volume of the aqueous solution to that of the non-miscible organic solvent and claimed crystallization rate, the reference is unspecified. However, the prior art does indicate that as a solvent system for the process, ethyl acetate, toluene, an acetic acid, methanol, ethanol, and water or those mixed solvents can be used 0.5 to 5 weight % to the aldehyde derivative (see page 3 ,paragraph 16). The limitation of a process with respect to ranges of ratio and rate does not impart patentability to a process when such values are those which would be determined by one of ordinary skill in the art in achieving optimum operation of the process. Ratio and rate are well understood by those of ordinary skill in the art to be a result-effective variable, especially when attempting to control selectivity in a chemical process.

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Regarding the packing density of 0.5 g/cm^3 of the crystalline optically active alpha-hydroxycarboxylic acid, the packing density is obtained naturally as a physical property in the course of evaluating the crystalline compound, not as a novelty of the claimed invention. Therefore, this does not have any patentable weight over the prior art.

Susumu et al does teach the process of producing the crystalline optically active 4-phenyl mandelic acid by reacting 4-phenyl benzaldehyde, potassium cyanides in the presence of concentrated hydrochloric acid in a solution of water and ethyl acetate at $80-85^\circ \text{C}$ to form the desired product(see page 3 , paragraph 30). 4-phenyl mandelic acid crystals in the resultant mixture have been recovered by crystallization , filtration, back washing by water and by drying. As a solvent system for the process, ethyl acetate, toluene, an acetic acid, methanol, ethanol, and water or those mixed solvents can be used 0.5 to 5 weight % to the aldehyde derivative. Furthermore, ratio is well understood by those of ordinary skill in the art to be a result-effective variable, especially when attempting to control selectivity in a chemical process in the absence of a unexpected result. Therefore, in order to control selectivity in a chemical process, it would have been obvious to the skilled artisan in the art to have motivated to modify the ratio between the volume of aqueous solvent and that of organic solvent in such a way as to maximize the solubility of mandelic acid crystals in the solvent system. This is because the skilled artisan in the art would expect the purity and the yield of the desired product to be increased by the ratio manipulation of the solvent system.

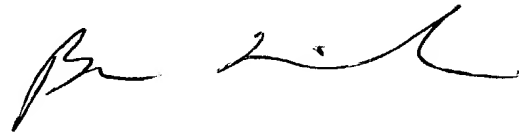
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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Mckane can be reached on 571-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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